Applicants: Hess et al.
Serial No. 10/034,060
Page 14

REMARKS

Claims 1-52 are pending in the application. Herein claims 40, 41, 43, 45, 47-50, 54, 60, 63-65, 68, 70-72 and 74 are amended, no claims are canceled, and no new claims are added.

The amendments submitted herewith are intended to place the application in condition for allowance, do not raise any new issues nor require additional searching by the Examiner.

Applicants respectfully request entry and favorable consideration of the present reply to final Office Action.

CLAIM REJECTIONS UNDER 35 U.S.C. §102

Claims 1-6, 19-26, 39, 40 and 51 are rejected as being anticipated under 35 U.S.C. §102(b) by U.S. Pat. No. 4,467,810 to Vollmann ("Vollmann"). Applicants respectfully traverse the rejections as enumerated hereinbelow. As is well known an anticipation rejection requires *each and every element of each claim be present in a single prior art reference.*

As stated by the Court of Appeals for the Federal Circuit: "A single prior art reference anticipates a patent claim if it expressly or inherently describes each and every limitation set forth in the patent claim." Trintec Indus. Inc. v. Top-U.S.A. Corp., 63 USPQ2d 1597, 1599 (Fed. Cir. 2002). "Inherent anticipation requires that the missing descriptive material is 'necessarily present,' not merely probably or possibly present, in the prior art." Id.

A patent is invalid for anticipation if a single prior art reference discloses each and every limitation of the claimed invention. Lewmar Marine, Inc. v. Barient, Inc., 827 F.2d 744, 747 (Fed. Cir. 1987). Moreover, a prior art reference may anticipate without disclosing a feature of the claimed invention if that missing characteristic is necessarily present, or inherent, in the single anticipating reference. Continental Can Co. v. Monsanto Co., 948 F.2d 1264, 1268 (Fed. Cir. 1991). Patent law nonetheless establishes that a prior art reference which expressly or inherently contains each and every limitation of the claimed subject

Applicants: Hess et al.
Serial No. 10/034,060
Page 15

matter anticipates and invalidates. See, e.g., EMI Group N. Am., Inc., v. Cypress Semiconductor Corp., 268 F.3d 1342, 1350 (Fed. Cir. 2001) ("A prior art reference anticipates a patent claim if the reference discloses, either expressly or inherently, all of the limitations of the claim."); Verdegaal Bros., Inc. v. Union Oil Co. of Cal., 814 F.2d 628, 631 (Fed. Cir. 1987) ("A claim is anticipated only if each and every element as set forth in the claim is found.

In the Office Action the entirety of the anticipation rejection formulated by the Examiner states, "Vollmann discloses a cardiac pacer comprising an atrial tachycardia response mode capable of automatically reapplying an atrial pacing therapy." No specific claim-by-claim analysis is presented in the Office Action, nor is any element-by-element analysis. Applicants respectfully suggest that the present rejection is per se in adequate and, in any event, the presently claimed invention is not anticipated by Vollmann.

After thorough review of Vollmann Applicants could not find support for the rejection. In fact, the following excerpts were about as much detail as could be culled from Vollmann. To wit

(from col. 12, lines 50-59):

> The maximum rate interval is used in detecting atrial tachycardia and therefore only applies to the atrial channel. Except in fallback mode, this channel is off during VVI pacing. The maximum rate interval places a ceiling on the intrinsic atrial rate, which the pacer will follow. If atrial pulses are so fast that they regularly precede the maximum rate interval, the pacer automatically enters the fallback pacing routine or executes 2:1 block, depending on which response mode is programmed. (emphasis added.)

(from col. 14, lines 38-44):

> Since in the VVI mode, no atrial stimulation is needed, the address of a "dummy" stimulation routine is loaded into the atrial stimulation pointer RD.1. Similarly, the addresses of the data for maximum rate, minimum rate and standard AV delay are entered. In addition the 2:1 block option is preselected by setting the fallback disable flag RC.1.

(from col. 15, lines 4-16):

Applicants: Hess et al.
Serial No. 10/034,060
Page 16

The main pacing routine is flow charted in FIG. 10. This routine is responsible for timing four intervals: the refractory period, AV delay, maximum rate, and minimum rate intervals. Tests for atrial and ventricular activity, if appropriate and if so programmed, determine whether to execute atrial or ventricular stimulation pulses. Except in VVI or 2:1 block mode, the main pacing routing keeps track of the number of atrial tachycardia events sensed between the end of the absolute atrial refractory period and the end of the maximum rate interval and determines whether to exit the main pacing routine and go to the fallback routine to respond to atrial tachycardia.

(from col. 17, lines 39-68):

The main pacing routine also monitors atrial tachycardia. The physician may select either fallback or 2:1 block as the atrial tachycardia response. If 2:1 block is programmed, the atrial refractory period is automatically set equal to the maximum rate interval. Thus in the 2:1 block mode, which is automatically preselected by STAT SET, the CPU is bound to find that the maximum rate interval has expired if the atrium has been sensed. If the intrinsic atrial rate exceeds the maximum rate, every second P-wave will fall in the refractory period and not be sensed.

If fallback is selected as the atrial tachycardia response, a more complex recognition scheme is employed. Although the atrial refractory period is absolute, if an atrial pulse is sensed between the end of the atrial refractory period and the end of the maximum rate interval, it is treated as a potential atrial tachycardia. The CPU employs the arrhythmia counter R3 to keep track of the relative frequency of atrial tachycardia. If an atrial sense output occurs during a scan cycle when the maximum rate interval has not yet expired, the arrhythmia counter is incremented twice. The same counter is decremented once whenever ventricular activity is sensed or ventricular output is generated. Thus the CPU makes a weighted value judgment to classify atrial tachycardia. Whenever the arrhythmia counter accumulates a count of six or more, the fallback response mode begins as the program branches to the fallback pacing routine.

Thus, Vollmann simply provides a counter that tracks atrial events that might be classified as an atrial tachycardia event in the "main pacing routine." However, the response to such an atrial tachycardia event is

Applicants: Hess et al.
Serial No. 10/034,060
Page 17

limited to only two alternatives, "2:1 block mode" or VVI "fallback mode."

As stated in the excerpt(s) above (esp. at col. 15, lines 4-16):

> "**Except in VVI [fallback mode] or 2:1 block mode**, the main pacing routing keeps track of the number of atrial tachycardia events sensed between the end of the absolute atrial refractory period and the end of the maximum rate interval..."

It should be very apparent that, unlike the presently claimed invention, Vollmann fails to offer any affirmative atrial tachycardia *pacing stimulation* response; in fact, by definition Vollmann *does not pace the atria* with its VVI fallback mode (i.e., v-pace/v-sense/inhibit) or its 2:1 block mode (which fails to log half of the atrial events and thus the ventricle tracks the atria at half the atrial rate — subject to a maximum ventricular rate limit). The presently claimed invention

Also, at claim 1 the following claim limitations are extant:

> means responsive to said arrhythmia signal for altering the mode of operation of said normal pacing logic means so as to disassociate the ventricles from the atria, and
> 2:1 block means for setting said atrial refractory period equal to said maximum rate interval,
> whereby every other atrial sense means output exceeding the maximum rate is inhibited and said arrhythmia signal is disabled.

The response to an atrial tachycardia event by a cardiac pacing according to Vollmann is simply to provide ventricular demand pacing (VVI fallback pacing) or pace the ventricles at half the atrial rate.

In contrast the presently claimed invention is directed to terminating an episode of atrial arrthymia with affirmative atrial pacing therapies. Applicants respectfully suggest that this difference alone is enough to distinguish the present invention from Vollmann.

No amendment made was related to the statutory requirements of patentability unless expressly stated herein; and no amendment made

Applicants: Hess et al.
Serial No. 10/034,060
Page 18

herein was for the purpose of narrowing the scope of any claim, unless
Applicants have argued herein that such amendment was made to
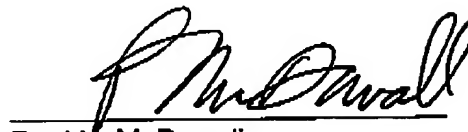distinguish over a particular reference or combination of references.

There being no further outstanding objections or rejections, it is
submitted that the application is in condition for allowance. An early action
to that effect is courteously solicited so that the claimed invention may
proceed to timely issuance as U.S. Letters Patent.

The Examiner is invited to contact the undersigned to discuss any
issues related to the present application.

Respectfully submitted,

Date: _10 Aug. 04_

Paul H. McDowall
Reg. 34,873
Telephone: (763) 514-3351
Customer No. 27581